LEXSEE 642 F.2D 413,AT 425

IN RE JOHN W. KELLER, JR., REESE S. TERRY, JR., and GOMER L. DAVIES

Appeal No. 80-573.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

642 F.2d 413; 1981 CCPA LEXIS 262; 208 U.S.P.Q. (BNA) 871

Oral argument on November 6, 1980

February 12, 1981

PRIOR HISTORY: [**1]

Serial No. 865,610.

COUNSEL:

Henry D. Pahl, Jr., Gilbert H. Hennessey, counsel for appellants.

Joseph F. Nakamura, Solicitor, Patent & Trademark Office, *Thomas E. Lynch*, of counsel.

OPINIONBY:

NIES

OPINION: [*414]

Before MARKEY, Chief Judge, RICH, BALDWIN, MILLER, and NIES, Associate Judges.

NIES, Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Appeals (board) in reissue application serial No. 865,610, filed December 29, 1977, n1 [*415] for "Digital Counter Driven Pacer." Claims 1, 2, 6, 7, and 9-16 (all of the claims in the application) stand rejected on the ground of a defective reissue declaration, and claims 1, 2, 6, 7, 9-11, 13, and 14 are rejected on the ground of obviousness in view of the following references:

n1 The application requests reissuance of U.S. Patent No. *3,557,796* issued January 26, 1971, on application serial No. 805,714, filed March 10, 1969, by Cordis Corporation, the assignee. Protests were filed against the reissue application by Cardiac Pacemakers, Inc. (CPI) and by Norman H. Stepno of the firm of Bacon & Thomas pursuant to the provisions of 37 CFR 1.291. A brief amicus curiae for protestor CPI was filed in this appeal. Two cases have been filed in the United States District Courts involving appellant's *'796* patent:

(1) Cordis Corp. v. Cardiac Pacemakers, Inc. and Edward J. Luczek, United States District Court, District of Massachusetts, Civil Action No. 77-3044-F (infringement action); and

(2) Cardiac Pacemakers, Inc. v. Cordis Corp., United States District Court, District of Minnesota, Fourth Division, Civil Action No. 4-77-427 (declaratory judgment action).

[**2]

Inventor	U.S. Patent No.	Issue Date
Keller, Jr. (Keller)	3,253,596	May 31, 1966
Berkovits	3,345,990	Oct. 10, 1967

Walsh and Moore (Walsh), The American Journal of Medical Electronics, First Quarter, 1966, pages 29-34. Claim 12 is allowable over the art of record but is objected to on the ground that the claim depends from a rejected claim. Claims 15 and 16 are allowable over the art of record. n2 We affirm in part and reverse in part.

n2 In addition to Keller, Berkovits, and Walsh, numerous other references were before the examiner. The examiner indicated in an Office Action dated May 8, 1978, however, that these other references were not any more pertinent than Keller, Berkovits, and Walsh.

Claims 1, 2, 6, 7, and 9-16 n3 are rejected under *35 USC 251* on the ground that the declaration made by applicant to support the reissue application does not particularly specify the prior art being brought to the attention of the examiner as required by 37 CFR 1.175(a)(4), does not particularly [**3] specify the errors relied upon by applicant and how the errors arose as required by 37 CFR 1.175(a)(5), and does not state that the errors arose "without any deceptive intention" on the part of applicant as required by 37 CFR 1.175(a)(6). n4

n3 Claims 1-12 were included in the reissue application as filed. By preliminary amendment claim 1 was amended and new claims 13 and 14 added. By subsequent amendment claims 3, 4, 5, and 8 were cancelled and new claims 15 and 16 added, the latter two claims reciting in independent form the same subject matter of cancelled dependent claims 5 and 8, respectively. Claims 9-12 were not amended during prosecution of the reissue application.

n4 37 CFR 1.175 (1980) reads, in pertinent part:

§ 1.175 Reissue oath or declaration.

(a) Applicants for reissue, in addition to complying with the requirements of the first sentence of § 1.65, must also file with their applications a statement under oath or declaration as follows:

(4) When the applicant is aware of prior art or other information relevant to patentability, not previously considered by the Office, which might cause the examiner to deem the original patent wholly or partly inoperative or invalid, particularly specifying such prior art or other information and requesting that if the examiner so deems, the applicant be permitted to amend the patent and be granted a reissue patent.

(5) Particularly specifying the errors or what might be deemed to be errors relied upon, and how they arose or occurred.

(6) Stating that said errors, if any, arose "without any deceptive intention" on the part of the applicant.

[24 FR 10332, Dec. 22, 1959, as amended at *29 FR 18503,* Dec. 29, 1964; *34 FR 18857,* Nov. 26, 1969; *42 FR 5594,* Jan. 28, 1977]

[**4]

Claims 1, 2, 6, 7, 9, 10, 11, 13, and 14 are rejected as unpatentable in view of Keller taken with Walsh. Claims 1 and 2 are further rejected as unpatentable in view of Berkovits taken with Walsh. The statutory basis of these rejections is *35 USC 103.*

The Invention

The claimed invention is a cardiac pacer having a digital counter.

As background, the specification explains:

In the normal heart, electrical signals are generated and appear in the atrium at a rate of approximately 60 to 120 times per minute, depending on such factors as body size and amount of physical exertion. Approximately 0.1 second after such a signal has appeared in the atrium, [*416] it is transferred to the ventricle of the heart, which reacts to the stimulation by contracting. This contraction forces blood from the ventricle into the arterial system and thence to the entire body. The delay between the appearance of an electrical signal in the atrium and its appearance in the ventricle is called the A-V delay. Following the contraction of the ventricle, there is an insensitive period lasting about 0.4 second, during which time the heart is unresponsive to electrical pulses. This time is referred [**5] to as the refractory delay period.

A common type of heart failure is irregularity in the generation of atrial potentials. In some cases, these potentials appear at only a low rate; in others, they cease entirely for extended periods though at other times the signals may be generated with perfect regularity. It is in persons suffering from this kind of cardiac disorder that a standby or so-called demand mode pacer is used. This device is designed to apply stimulating pulses to the ventricle, by means of an electrode implanted therein, only when the heart fails to generate pulses spontaneously. When natural pulses regularly appear, the pacer provides no stimulation; when they appear irregularly, the pacer adjusts its timing to integrate its artificial pulses with the natural ones. This type of pacer is often provided with circuitry which simulates the refractory delay period of the heart. The reason for including such delay circuitry is that

a spontaneous electrical signal which appears a short time after delivery of an artificial pulse is ineffective to pump blood, either because the natural refractory period of the heart caused the heart to ignore the spontaneous pulse or [**6] because the ventricle has not had time following the previous beat to be refilled with blood. A simulated refractory period causes the pacer likewise to ignore these ineffective beats. The device's timing continues just as if the beats had never occurred.

Another form of heart disease is the so-called A-V block in which the patient's heart undergoes normal or near-normal atrial contraction but the atrial signal is not transferred to the ventricle. With such a patient, it is desirable to use a so-called synchronous pacer which detects atrial signals and supplies to the ventricle a stimulating pulse about 0.1 second later, a period which constitutes a simulated A-V delay. In the absence of detected atrial signals, the pacer supplies ventricular pulses at a fixed rate. The synchronous pacer, like the demand paper, is often provided with refractory delay simulation.

Summarizing the invention, the specification states:
[A] cardiac pacer according to the present invention times various events and delays by means of a digital counter which is driven by an oscillator operating at a frequency which is a relatively large multiple of a normal heartbeat rate. A cardiac stimulating [**7] pulse is generated at a predetermined point in the count. Thus, if the counter cycles repetitively, the heart is stimulated at a predetermined fixed rate. To provide demand mode operation, the counter is reset in response to spontaneous cardiac signals thereby to prevent stimulation when the heart is functioning normally. To provide synchronous mode operation, the counter is reset to a point preceding the stimulation count by an amount which simulates a normal A-V delay.

The use of digital count down circuitry permits both the various delays and the durations of the stimulating pulses to be accurately timed. Further, by counting down from a relatively high frequency, an oscillator having a relatively short duty cycle may be used so as to reduce battery drain. Further, the use of a relatively short oscillator period permits timing components, e.g., capacitors, of relatively small size to be used.

A block diagram of a cardiac pacer, according to the present invention, appears below:

[See original.] [*417]

The specification indicates that if the pacer is to operate in the demand mode in a particular patient, an output electrode implanted in the patient's heart at [**8] a location suitable for stimulating ventricular contractions is connected to output terminal 6 of the pacer. If the pacer is to operate in the synchronous mode in a particular patient, an output electrode implanted in the patent's heart at a location suitable for stimulating ventricular contractions is connected to output terminal 9 of the pacer.

According to the specification, for demand mode operation an input electrode implanted to detect ventricular signals of the patient's heart is connected to input terminal 10 of the pacer. For synchronous mode operation, an input electrode implanted to detect atrium signals of the patient's heart is connected to the input terminal 10. "Cardiac signals applied to the input terminal 10 are amplified and shaped by means of an amplifier 11 so as to be squared into waveforms suitable for use with digital circuitry, as is understood by those skilled in the art."

The timing of the different events occurring in the operation of appellant's pacer is provided by a digital counter 3.
The counter is driven by an oscillator 1 which establishes the time base. As illustrated, counter 3 comprises a nine stage binary divider and the oscillator 1 [**9] runs at a frequency which is relatively high with respect to the contemplated range of heartbeat rates or frequencies....

As is conventional, counter 3 provides a two-stage output signal for each stage of binary division...

As is also conventional, the counter 3 runs cyclically, that is, the states of the binary output signals pass through a sequence which repeats after all the possible combinations have been utilized... Further, the counter may at will be reset to a predetermined starting point by the application of a reset signal to a reset terminal, designated R. The starting point of the counter is considered herein to be the zero count and the various possible states or counts are considered to be zero through 511. n5

> n5 Consequently, the counter counts as follows: 0, 1, 2, 3,..., 509, 510, 511, 0, 1, 2,..., that is, the count changes from "511" to "0".

In describing operation of the pacer in the demand mode, the specification states that:
... if the patient's heart is beating normally at [**10] a rate which is more than the free running rate of the pacer, i.e. about 70 beats per minute, and not more than twice that rate, i.e. about 140 beats per minute, the counter 3 will be reset to its zero count by each natural heartbeat before a count of 511 is reached. Thus, the patient's heart will not be stimulated at all if it is beating spontaneously within this 2-to-1 range of rates. However, if no spontaneous heartbeat is detected between count 256 and count 511, the pacer will then stimulate the patient's heart at the end of the full count period, that is, after a period which corresponds to the 70 pulse per second free running rate.

In other words, the difference between the starting point count and the end of the counting sequence establishes a maximum interval between heartbeats. Accordingly, if the spontaneous heart signals disappear intermittently, the pacer [*418] will integrate its operation with the normal heartbeat.

In describing operation of the pacer in the synchronous mode, the specification states:
The resetting of counter 3 is controlled in response to detected signals as described previously. Thus, the counter is reset to its zero count if an atrial [**11] signal is detected from count 256 through count 511. A stimulating pulse is then generated at output terminal 9 when count 64 is reached. The delay provided by the interval between the resetting and the 64 count is about 108 milliseconds which satisfactorily simulates the normal A-V delay. Thus the heart is stimulated with timing appropriate for synchronous pacer operation.

If no atrial signals at all are detected, the counter 3 will run cyclically as described previously and stimulating pulses will be generated at a fixed rate, one pulse being generated each time the counter 3 passes the 64 count.

The specification describes the digital timing circuit in more detail than set forth above. The claims rejected on prior art, however, do not recite such detail. Claims 1 and 13 are illustrative:

1. Cardiac pacer apparatus comprising:
an oscillator providing a pulsating signal at a preselected frequency, which preselected frequency is a relatively large multiple of a normal heart beat rate;
a cyclically operating digital counter means for counting the pulsations of said pulsating signal;
means controlled by said counter for generating a cardiac stimulating potential when [**12] said counter reaches a predetermined count;
means for detecting a naturally occurring heart beat; and
means for setting said counter to a preselected value when a naturally occurring heart beat is detected. [Paragraphing added.]
13. Cardiac pacer apparatus comprising:
an oscillator providing a pulsating signal at a preselected frequency, which preselected frequency is a relatively large multiple of a normal heart beat rate;
a cyclically operating digital counter means for counting the pulsations of said pulsating signal;
means controlled by said counter for generating a cardiac stimulating potential when said counter reaches a predetermined count;
means for detecting cardiac signals generated during a heart beat; and
means responsive to such detected cardiac signals for setting said counter to a starting point count which precedes said predetermined count by a number corresponding to a preselected maximum interval between successive heartbeats whereby a stimulating potential is generated only if said preselected maximum interval elapses between heart beats. [Paragraphing added.]

The References

The Keller '596 Patent

Keller relates to a transistorized, implantable [**13] cardiac pacer for regulating an animal heart. The specification states that a pacer according to the Keller invention includes:
... sensing means responsive to a physiological heart pacing signal for producing a trigger signal, means for delaying said trigger signal for a period substantially equal to a normal attrial-ventricular delay, n6 a two-state free running oscillator one state of which can be terminated by the arrival of a delayed trigger signal and the other state of which is unaffected by the arrival of a signal, means responsive to the return of said oscillator to said one state for producing ventricular stimulation, whereby the minimum rate at which the pacer operates is determined by the [*419] natural period of the oscillator and the maximum rate at which said pacer can operate is determined by the natural duration of said other state, the natural durations of each of said states being independently predeterminable, and the arrival of delayed trigger signals at frequencies between said minimum and maximum synchronously controls said oscillator.

> n6 According to Keller, the atrial-ventricular (A-V) delay is approximately two-tenths of a second in man, and less in smaller animals.

[**14]

Indentifying the elements described in the Keller patent, the examiner found the Keller pacer includes:
a pulse generator (comprising blocking oscillator 40, stimulating pulse generator 50, and output amplifier 60);
an analog time base circuit included in the pulse generator for generating a cardiac stimulating potential at a predetermined time (comprising transistors T5, T6);
means for detecting cardiac signals (comprising amplifying circuit 10, 20);
reset means for setting the analog time base circuit to a starting point (comprising diode D2); and
means for inhibiting the resetting during a preselected refractory delay period which ends at a time after the starting time but before the stimulus generating time (comprising delay circuit 30).
Appellant has not disputed these findings.

The Keller pacer can operate in a synchronous mode

and in an asynchronous free-running mode. In the synchronous mode, an atrial signal is sensed, amplified, and processed, and a ventricular stimulation pulse produced and applied to the heart a predetermined time after the occurrence of the atrial signal. This predetermined time corresponds approximately to the normal A-V delay. If [**15] atrial signals are sensed to occur at a dangerously high rate, the pacer operates in the synchronous mode to produce and apply ventricular stimulation pulses at a predetermined maximum rate. If atrial signals are not sensed or are too weak for synchronization purposes, the pacer operates in the asynchronous free-running mode to produce and apply ventricular stimulation pulses at a predetermined minimum rate. n7

n7 The minimum rate is 60 pulses per minute for a human patient.

Both the sensing of the atrial signal and the application of ventricular stimulation are accomplished by electrodes implanted in the patient's heart.

The Berkovits '990 Patent

Berkovits relates to a cardiac pacer for regulating a heart. The specification states that a pacer according to the Berkovits invention includes: means for accurately monitoring the beating action of a human heart; means for providing corrective electrical stimulation of the beating action of an abnormal heart; and means for automatically effecting such corrective [**16] heart stimulation only where required as determined by the means for monitoring the heart. The Berkovits pacer functions to "furnish stimulation to an abnormal heart in such a manner that heartbeats are individually stimulated and closely integrated with natural heartbeats."

Identifying the elements described in the Berkovits patent, the examiner found the Berkovits pacer includes:
an analog time-base pulse generator (comprising heart stimulating means 12 and pulse generating means 18);
means for detecting a naturally occurring heartbeat (comprising detecting means 14 and amplifying means 16); and
means for restarting the timing period when a naturally occurring heartbeat is detected (comprising triode clipper 122).
Appellant has not disputed these findings.

The Berkovits pacer is not implantable. The monitoring means 10 includes electrocardiograph means 14 for detecting electrical signals developed by the heart during natural heartbeat action, vacuum tube amplifier means 16 for amplifying these natural heart signals, vacuum tube pulse generating means 18 responsive to the amplified signals for sending control signals to vacuum tube heart stimulating means 12, and may [**17] also include oscilloscope means 20 and audible signal means 22 for providing visual [*420] and audible indications of the occurrence of natural and stimulated heartbeats.

The heart stimulator 12 is equipped with a double-pole triple-throw switch 177 which permits manual selection of the mode of operation of the heart stimulator. Berkovitz states:
When the movable switch arms 178, 180 [of switch 177] are set on the fixed contacts 182, 184, respectively, the heart stimulator will not be operative... [W]hen the movable arms are set on the fixed contacts 186, 188, the heart stimulator is adapted to provide a continuous series of heart stimulating electrical impulses at a predetermined rate which is independent of natural heartbeats occurring at the same time. ... [W]hen the movable arms are set on the fixed contacts 190, 192... the heart stimulator is adapted to provide heart-stimulating electrical impulses only in closely integrated relation to natural heartbeats... so that stimulated and natural heartbeats can each contribute to maintenance of a predetermined heartbeat rate. Electrodes 218 of any conventional type... can be employed for applying a relatively large [**18] heart stimulating pulse to the patient's heart from outside the patient's body whereas the electrodes 220 can be surgically connected to the patient's heart for applying a relatively smaller electrical impulse directly to the patient's heart when desired.
Variable resistor 210 of the heart stimulating means 12 is used to selectively vary the amplitude of the heart stimulating pulse to be applied to the heart through electrodes 218 and 220.

We note that, in addition to the mode selection switch 177 and the stimulating pulse amplitude adjustment control 210 included in the heart stimulating means 12, the amplifier means 16 includes a polarity-reversing switch 32, a bias circuit switch 62, a variable voltage divider 116 which serves as a center control for the oscilloscope means 20, and a variable voltage divider 106, 108 which serves as an amplifier gain control. It is apparent from the Berkovits disclosure as a whole that these switches and variable circuit elements are operator controlled.

The Walsh and Moore Article

Walsh relates to a stimulator driving unit for the controlled stimulation of the heart of a mammal. The disclosed driver includes a digital timing circuit. [**19] Walsh states:

A digital timing system was used since it provides a higher degree of accuracy and resetability than the R-C type circuits used in conventional stimulators. In this sys-

tem, a crystal-controlled, time-base generator provides a standard from which to derive the various intervals. A crystal frequency [of 0.1 megahertz] was chosen to provide a 10-u sec time base. The output of this circuit was amplified, shaped and fed to a series of six digital counting modules that make up the timing chain controlling intervals between stimuli.

The examiner found that Walsh discloses:
... the conventional expedient of providing a digital time base means for a medical stimulator by employing an oscillator having a frequency much higher, such [as] a relatively large multiple of the stimulation pulse frequency and counting means to produce a stimulating pulse at the desired frequency.
Appellant has not disputed these findings.

The Rejections

Reissue Declaration Rejections

The examiner rejected claims 1, 2, 6, 7, 13-16 (the claims that were either amended or added during prosecution of the reissue application) under *35 USC 251* as based on an insufficient reissue declaration. [**20] The declaration which accompanied the reissue application reads, in pertinent part:

I, William P. Murphy, Jr., Chairman of the Board of Directors of Cordis Corporation, declare
[1.] that subsequent to the issuance of U.S. Letters Patent No. *3,557,796*, [*421] applicant has, in connection with the prosecution of corresponding foreign patent applications, been made aware of prior art relevant to patentability not previously considered by the Patent Office, which prior art might cause the Examiner to deem the original patent wholly or partly inoperative or invalid;
[2.] that this new prior art is particularly specified in a citation of prior art accompanying this reissue application;
[3.] that, to the extent the [preliminary] amendment [filed herewith] might be deemed to correct errors in the original patent, such errors arose without any deceptive intent or purpose upon the part of applicant;...
/s/ William P. Murphy, Jr.

Date: Dec. 24, 1977
The "citation of prior art" referred to in the declaration and filed with the declaration reads, in pertinent part:

The following prior art has become known to applicant subsequent to the issuance of the original Letters [**21] Patent No. *3,557,796* and is being brought to the attention of the Patent and Trademark Office for its consideration in connection with this reissue application.

The references are:

Copies are enclosed.

/s/ [Attorney for Applicant]

December 23, 1977

In making these rejections, the examiner stated that "applicants [sic] have not particularly specified all the changes in the claims [as set forth in the preliminary amendment] as the errors nor have they stated how they [the errors] arose or occurred."

The board affirmed the examiner and stated that
the declaration fails to particularly specify the newly discovered prior art. Reference to another paper to be filed in the application is inadequate to fulfill this requirement. The board further indicated that the declaration not only failed to comply with 37 CFR 1.175(a)(4), but also failed to comply with 37 CFR 1.175(a)(5) and (a)(6). n8 Accordingly, pursuant to 37 CFR 1.196(b), n9 the board rejected claims 9-12 (the claims that were neither amended nor added during prosecution of the reissue application) under *35 USC 251* as based on a declaration which does not comply with 37 CFR 1.175(a)(4), (a)(5), and (a)(6). [**22]

n8 See note 4, supra.

n9 37 CFR 1.196 (1980) reads, in pertinent part:

§ 1.196 Decision by the Board of Appeals.

(b) Should the Board of Appeals have knowledge of any grounds not involved in the appeal for rejecting any appealed claim, it may include in its decision a statement to that effect with its reasons for so holding, which statement shall constitute a rejection of the claims.
[24 FR 10332, Dec. 22, 1959, as amended at *42 FR 5595,* Jan. 28, 1977]

Prior Art Rejections

The examiner rejected claims 1, 2, 6, 7, 9-11, 13, and 14 as obvious in view of Keller taken with Walsh. He stated:

The claims define over the Keller, Jr. patent in the recitation of a digital time base pulse generator. Walsh et al discloses in Figure 3 the conventional expedient of providing a digital time base means for a medical stimulator by employing an oscillator having a frequency much higher, such as a relatively large multiple of the stimulation pulse frequency and counting means to produce a stimulating pulse [**23] at the desired frequency.

Providing an oscillator and counter-type digital time base generator for its analog equivalent in the Keller, Jr. et al device amounts to an obvious substitution to one of ordinary skill in the art after consideration of the prior art

taken as a whole. [*422]

The examiner further rejected claims 1 and 2 as obvious in view of Berkovits taken with Walsh. He stated that it would have been obvious in view of the teachings of Walsh to employ digital timing circuitry with a relatively high frequency oscillator in the Berkovits pacer in place of the analog timing circuitry.

Neither Keller nor Berkovits nor Walsh were cited during prosecution of the original patent application.

Rebuttal Evidence

To rebut the prima facie case of obviousness established by the examiner, appellant filed an affidavit of Jozef K. Cywinski, Ph.D. This affidavit, according to appellant, "concerns itself mainly with the question of whether the Walsh et al article suggest [sic] the use of digital timing in a cardiac pacer...."

Dr. Cywinski, an expert in the cardiac pacer art, states in this affidavit:
In 1967... I met Neil Moore [co-author of Walsh] and learned [**24] of a digital timing unit which he and Leon Walsh had built and were using for their stimulation studies....I have been shown a 1966 article [Walsh]... I recognized the apparatus referenced therein as being that which was described to me [by Moore] in 1967 or 1968. At this time (1967-1968), I was also aware of other medical research devices employing digital counters as timing chains.

Even before this period, it was becoming increasingly common to employ digital timing techniques in research environments. The digital approach was indicated where precise incremental timing was needed or where considerable flexibility and repeatable adjustments were needed. These characteristics are typically needed in investigatory or research projects.

Of the various prior art laboratory timing devices employing digital counting chains, it should also be noted that these were largely operator-controlled devices...

Although I was thus quite familiar with the use of digital timing devices as laboratory instruments, I was nonetheless impressed with the novelty of the digital cardiac pacer, being developed by Cordis, which was first described to me by John Walter Keller in about 1970 in [**25] a form of a personal communication. This pacer is described and claimed in U.S. Patent No. *3,557,796.* At the time, I did not regard the approach described to me by Keller as being obvious. Rather, I believed that the approach would not have been obvious even to try since the complexity would seem to outweigh the advantages of digital timing. Further, the usual advantages, i.e., exceptional precision and incremental adjustability, were not ones which would appear to have particular utility in cardiac pacers. Rather, the simplicity of the usual analog timing circuit would seem to offer the clear advantages. I should note that I was, at that time, also familiar with the Cordis synchronous pacer which is disclosed and claimed in Keller Patent No. 3,253,596 and also the American Optical standby pacer, an earlier version of which is disclosed and claimed in Berkovits Patent No. 3,345,990.
The Cordis pacer is a therapeutic device rather than a research tool and, further, is interactive with the spontaneous action of the patient's heart. The device disclosed in the Moore et al article does not in any similar way respond to naturally occurring heart signals nor am I aware of any other [**26] prior art device in which a digital counting chain is present in response to a naturally occurring heartbeat. * * * The heart being stimulated [in Walsh] is an object of study, not an organism being aided in its natural function. * * *
I do not find in the Walsh et al article any suggestion that these attributes [higher degree of accuracy and resetability when digital timing circuitry is used instead of analog timing circuitry] [*423] would be advantageous in a cardiac pacer.

A cardiac pacer is implanted in the human body to monitor and control... the heart... to continue the life of the patient... with no wire connections to the world outside the patient's body.
[O]ne skilled in the art at the time of the Keller et al invention would not expect that it would be either desirable or advantageous to use complicated digital circuitry. Nor would one appreciate the great advantage of the digital approach, an approach which in practice has now become recognized by the industry. [Emphasis added.]

No other rebuttal evidence was offered. The examiner did not present any additional evidence in response to the affidavit.

Board Opinion

The board unanimously affirmed [**27] the rejection of claims, 1, 2, 6, 7, and 13-16 under *35 USC 251,* and entered the rejection of claims 9-12 on the same ground.

The board was divided regarding the art rejections. Two members found the affidavit insufficient to overcome the prima facie case of obviousness established by the examiner and affirmed these rejections. The majority opinion states that the affiant's statements "that he was impressed with the novelty, did not regard the approach as being obvious and believed that the approach would not have been obvious even to try... [are] statements [of] affiant's opinion on the ultimate legal issue and, therefore, are entitled to little weight [citations omitted]."

Regarding Dr. Cywinski's factual statements about the

prior art, the opinion states:

The points made by affiant are welltaken but, to a large extent not germane to the claimed subject matter or the rejections under section 103... [The affiant] addressed himself to the intended purpose, and, undoubtedly the actual commercial purpose, of the claimed subject matter. However, the claims are not directed to a therapeutic cardiac pacer which is to be implanted into a human body to monitor and control [**28] the heart in order to continue the life of the patient. The claims are broad enough to encompass a device for use on animals in a research laboratory...

The board held:
Keller and Berkovits both disclose cardiac pacers which function in a manner similar to the appellants' pacer using an analog timer. Walsh discloses a heart stimulator wherein a digital timer is used. The motivation for using a digital timer in place of the analog timer in the Keller and Berkovits pacers is found in Walsh where it is stated, at page 30, that digital timers provide a higher degree of accuracy as compared with analog timers.
The rejections under section 103 are predicated on replacing the analog R-C timing means in Keller and Berkovits with an equivalent digital timer; not on combining the Walsh device with the Keller or Berkovits pacer or substituting the Walsh device for the R-C timing circuit of Keller or Berkovits... The fact that the Walsh reference makes no mention of pacing a heart or that the Walsh device does not respond to naturally occurring heart signals is immaterial. The Walsh reference is only relied on for the teaching of digital timing in an analogous environment; the other [**29] features are disclosed in Keller and Berkovits. [Emphasis added.]

The third member of the board found the affidavit sufficient to overcome the prima facie case of obviousness established by the examiner. He stated that the affiant makes "several pertinent statements which must be considered as facts because they are being made by an expert and cannot be dismissed as mere opinion." He also stated that "to say in the claims that the cardiac pacer is to be implanted in a human being to monitor and control the heart for the purpose of sustaining life would be, in my opinion, redundant." [*424]

OPINION

Appellant does not argue that any features of the rejected claims other than the use of digital timing are not disclosed in Keller and Berkovits. Thus, the sole issue regarding the prior art rejections is essentially whether the references, taken collectively, would have suggested the use of digital timing in a cardiac pacer to those of ordinary skill in the art at the time the invention was made. n10

n10 Miniaturization of the physical size of the circuitry used in a cardiac pacer, the use of integrated circuit techniques in such circuitry, the elimination of hand-wired circuit interconnections in such circuitry, and so forth are not in issue. These features are not claim limitations. Moreover, appellant admits that
... integrated circuits were used in analog pacers and an integrated circuit amplifier was incorporated in the first digitally timed cardiac pacer made by Cordis Corporation... The choice between analog timing and digital timing was thus made largely independently of the move to integrated circuits.

[**30]

Appellant argues essentially three points:
(1) the teachings of Walsh cannot properly be combined with those of either Keller or Berkovits because Walsh does not relate to a cardiac pacer;
(2) if the digital timing circuitry taught by Walsh is incorporated in either the Keller pacer or the Berkovits pacer, the resulting structure would not fairly meet the claims in issue; and
(3) the board did not "accord appropriate weight to" Dr. Cywinski's affidavit, but rather "completely set aside", "disregarded", and "ignored" his statements therein.
Definition of Cardiac Pacer

The claims are directed to cardiac pacer apparatus. A cardiac pacer is defined as:
... a device designed to stimulate, by electrical impulse, contractions of the heart muscle at a certain rate; used in absence of normal function of the sino-atrial node; it may be connected from the outside or implanted within the body. n11

n11 Dorland's Illustrated Medical Dictionary 1080-81 (24th ed. 1965), defining "pacemaker." This definition is carried forward in the subsequent edition, Dorland's Illustrated Medical Dictionary 1117-18 (25th ed. 1974), and augmented with examples of external types and implanted types of pacers.

[**31]
On its face, Keller relates to a cardiac pacer which is implanted within the body. On its face, Berkovits relates to a cardiac pacer which is not implantable within the body, but rather is connected from the outside of the patient's body.Appellant admitted below that "[b]oth the Keller '596 patent and the Berkovits '990 patent disclose cardiac pacers...," and asserted that these patents "represent conventional thinking with respect to cardiac pacing

at the time the present invention was made." Appellant admitted further that "the Keller et al and Berkovits devices are true interactive cardiac pacers...." Thus, the term "cardiac pacer" encompasses both implantable and non-implantable devices. Therefore, the words "cardiac pacer apparatus" used in the rejected claims are broad enough to read on a device for humans which is not implanted. n12

n12 Dr. Cywinski, who indicated that he was familiar with the pacers "disclosed and claimed" in Keller and in Berkovits, stated: "A cardiac pacer is implanted in the human body to...." We note Dr. Cywinski did not state that a device cannot be a cardiac pacer if it is not implanted in the human body, and we further note that, based on his familiarity with the pacer disclosed and claimed in Berkovits (which is not implantable), he could not have intended his testimony to be so construed.

[**32]
Walsh Relates to Analogous Art

Contrary to the position advanced by appellant on appeal, Keller and Berkovits are the principal references relied on by the examiner in his rejections. n13 Walsh is the secondary reference. The board correctly noted that Walsh is relied on only for the teaching of digital timing in an analogous environment.

n13 Appellant, at page 6 of his main brief, states: "... the type described in the principal reference, the Walsh et al article."

Appellant "strongly emphasizes" that Walsh "is not about cardiac pacing"; and that the device taught by Walsh is an [*425] investigatory device used in the study of a mammalian heart rather than a therapeutic device used in the treatment of a living human (which, of course, has a mammalian heart).

Walsh discloses a heart stimulator used in studies of the atrioventricular conduction system of a mammalian heart. A stimulator used in studies of the atrioventricular conduction system of a mammalian heart is not so non-analogous to a [**33] stimulator used to pace a mammalian heart that it should be ignored. Accordingly, Walsh may be combined with either Keller or Berkovits. *In re Menough, 51 CCPA 741, 323 F.2d 1011, 139 USPQ 278 (1963).*

Appellant further argues that Walsh does not relate to a cardiac pacer because Walsh teaches a stimulator which is used in conjunction with an oscilloscope, and which has a multiplicity of multiple position switches that are operator controlled. As discussed above, Berkovits discloses a cardiac pacer which may be used in conjunction with an oscilloscope, and which has a multiplicity of multiple position switches as well as other variable circuit elements that are operator controlled. Thus, the argument that such features render Walsh unrelated to a cardiac pacer is without merit.
Combining Walsh with Keller or Berkovits

To justify combining reference teachings in support of a rejection it is not necessary that a device shown in one reference can be physically inserted into the device shown in in the other. *In re Griver, 53 CCPA 815, 354 F.2d 377, 148 USPQ 197 (1966); In re Billingsley, 47 CCPA 1108, 279 F.2d 689, 126 USPQ 370 (1960).* The test for obviousness is not whether the [**34] features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Wood, 599 F.2d 1032, 202 USPQ 171 (CCPA 1979); In re Passal, 57 CCPA 1151, 426 F.2d 828, 165 USPQ 720 (1970); In re Richman, 57 CCPA 1060, 424 F.2d 1388, 165 USPQ 509 (1970); In re Rosselet, 52 CCPA 1533, 347 F.2d 847, 146 USPQ 183 (1965).*

Both Keller and Berkovits disclose heart stimulators that use R-C type timing circuits. Walsh teaches the use of digital type timing circuits in place of R-C type timing circuits in conventional heart stimulators. Therefore, the question is whether it would have been obvious to one of ordinary skill in the art, working with the Keller and the Berkovits and the Walsh references before him, to do what the inventors herein have done, that is, to use a digital timing circuit in a cardiac pacer. *In re Winslow, 53 CCPA 1574, 365 F.2d 1017, 151 USPQ 48 (1966),* as modified by *In re Antle, 58 CCPA 1382, 444 F.2d 1168,* [**35] *170 USPQ 285 (1971).* We agree that the references establish a prima facie case of obviousness.
The Cywinski Affidavit

Once a prima facie case of obviousness was established below, the burden shifted to appellant to rebut it, if he could, with objective evidence of non-obviousness. *In re Fielder, 471 F.2d 640, 176 USPQ 300 (CCPA 1973).* Appellant attempted to do so by introducing the Cywinski affidavit. Both this court and the PTO must give full consideration to that evidence and render a decision based on the relative strength of appellant's showing and the prima facie case established by the references. *In re Saunders, 58 CCPA 1316, 444 F.2d 599, 170 USPQ 213 (1971).*

Appellant's showing below "may well shift the burden

of proof to the examiner to then come forward with further support for his conclusion that the invention would be obvious under the conditions stated in section 103." *In re Katzschmann, 52 CCPA 1497, 1500, 347 F.2d 620, 622, 146 USPQ 66, 68 (1965).*(Emphasis added.) Whether appellant's showing does shift the burden of proof, however, must be determined on a case by case basis.

As characterized by appellant, the Cywinski affidavit offered as objective evidence [**36] of non-obviousness "concerns itself mainly [*426] with the question of whether the Walsh et al article suggest [sic] the use of digital timing in a cardiac pacer...." But one cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references. *In re Young, 56 CCPA 757, 403 F.2d 754, 159 USPQ 725 (1968).* Moreover, as set forth above, the test is not whether a suggestion to use digital timing in a cardiac pacer is found in Walsh (which was the test applied by Dr. Cywinski), but rather what Keller in view of Walsh and what Berkovits in view of Walsh would have suggested to one of ordinary skill in the art.

Contrary to the position advanced by appellant, *In re Carroll, 601 F.2d 1184, 202 USPQ 571 (CCPA 1979)* is not "nearly 'on fours' with the present factual situation."

In Carroll this court concluded that the opinion of an expert on what the prior art taught was deserving of considerable deference under the circumstances of that case. The expert had critically reviewed the sole piece of prior art and totally discounted its value. The accuracy of the expert's views was supported by documentary evidence. [**37]

In the present case, we are not presented with a single prior art reference, but rather two combinations of three references: Keller in view of Walsh, and Berkovits in view of Walsh. The affidavit does not indicate that Dr. Cywinski critically reviewed the use of digital timing in a cardiac pacer as prima facie established by the two combinations of references. Consequently, Dr. Cywinski's opinion on the ultimate legal question of obviousness is entitled to little weight.

Section 103 Rejections are Affirmed

The board considered Dr. Cywinski's testimony and accorded it due weight. We are satisfied that the record herein contains sufficient evidence to support the board's decision. Accordingly, we affirm the decision of the board regarding the § 103 rejections.

Requirements of Reissue Declaration

Turning to the rejections under *35 USC 251,* we note that a reissue declaration, defective in the nature alleged herein, is correctable in the PTO by the filing of a supplemental oath or declaration.

A reissue oath or declaration filed under 37 CFR 1.175 subsection (a)(4) must also comply with both subsections (a)(5) and (a)(6). n14 Subsection (a) of section 1.175 sets forth [**38] requirements relating to the content of a statement which must be filed by the applicant with his reissue application. Subsection (a)(4), which requires the applicant to particularly specify the prior art or other information relevant to patentability and not previously considered by the PTO, which might cause the examiner to deem the original patent wholly or partly inoperative or invalid, therefore requires the prior art or other information to be specified in that statement.

n14 See note 4, supra.

In the present case, the reissue declaration purported to incorporate by reference a paper entitled "citation to prior art" on which the prior art being brought to the attention of the PTO by the applicant was delineated. The question before this court, therefore, is whether the citation of prior art was successfully incorporated by reference into the declaration.

Subsection (a) of section 1.175 requires the statement to be made by the applicant under oath or declaration. This statement, therefore, (1) must [**39] be subscribed to by the applicant, and (2) must either (a) be sworn to or affirmed by the applicant as provided in 37 CFR 1.66, or (b) include the personal declaration of the applicant as prescribed in 37 CFR 1.68. See 37 CFR 1.65(a)(2).

In the present case, the declaration per se was subscribed by the applicant and included an appropriate personal declaration of the applicant. The citation of prior art was not subscribed by the applicant and did not include the personal declaration of the applicant.Rather, the citation of prior art was subscribed by applicant's attorney. And, while the citation of prior art is dated [*427] one day earlier than the declaration, there is no evidence in the record that applicant even saw the citation of prior art at the time the declaration was executed.

Accordingly, we affirm the decision of the board regarding the rejections of claims, 1, 2, 6, 7, and 9-16 under *35 USC 251* because the declaration does not comply with 37 CFR 1.175(a)(4).

As to the rejections on grounds relating to 37 CFR 1.175(a)(5) and (a)(6), we do not agree with the board.

Subsection (a)(5) requires the applicant to specify "the errors or that might be deemed to [**40] be errors relied upon, and how they arose or occurred." Subsection 1414.03 of the Manual of Patent Examining Procedure (MPEP) (4th ed., Rev. 1, Jan. 1980) n15 states that to comply with the requirements of subsection (a)(5) in a §

1.175(a)(4) type reissue, the reissue declaration

> n15 We note that MPEP chapter 1400, the chapter dealing with reissue applications, has been completely revised in the fourth edition and now includes detailed instructions regarding, inter alia, reissue declarations.

might state that some or all claims might be deemed to be too broad and invalid in view of references X and Y which were not of record in the patent files. Usually, a general statement will suffice. * * * [The reissue declaration] must indicate when and the manner in which the reissue applicant became aware of the prior art or other information...

MPEP § 1401.08 (3rd ed., Rev. 54, Oct. 1977) merely stated:

The reissue oath or declaration must point out very specifically what the defects are and how the errors [**41] arose.

Applicant's reissue declaration contains a passage (which we have numbered "1" in the quoted declaration) that is remarkably close to what subsequently appeared in the fourth edition of the MPEP with respect to the content of a declaration for this purpose. We hold on the facts of this case that the declaration fairly meets the requirements of 37 CFR 1.175(a)(5).

Subsection (a)(6) requires the applicant to state that said errors, if any, arose without deceptive intention on the part of the applicant. The passage in the declaration which we have numbered "3" fairly meets this requirement.

CONCLUSION

Accordingly, the decision of the board regarding the rejections of claims 1, 2, 6, 7, 9-11, 13, and 14 based on the prior art is affirmed, the decision of the board regarding the rejections of claims 1, 2, 6, 7, and 9-16 based on 37 CFR 1.175 subsection (a)(4) is affirmed, and that based on subsections (a)(5) and (a)(6) is reversed.

MODIFIED